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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,592	06/16/2000	Heinrich Wieland	1378.001US1	4572

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EXAMINER

HWU, JUNE

ART UNIT	PAPER NUMBER
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1661

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/597,592	WIELAND ET AL.	
	Examiner	Art Unit	
	June Hwu	1661	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 18-33 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/2/01 & 6/4/01</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1661.

The preliminary amendment filed June 16, 2000 has been acknowledged. The declaration filed February 11, 2002 has been acknowledged.

Foreign Priority

Acknowledgment is made of applicants' claim for foreign priority based on an application filed in Germany on December 17, 1997. It is noted, however, that applicants have not filed a certified copy of the German application as required by 35 U.S.C. 119(b).

Election/Restrictions

During a telephone conversation with Attorney Patrick Gattari on April 22, 2004 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-17 and 35. Affirmation of this election must be made by applicants in replying to this Office action. Claims 18-33 and 36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claims 1, 3, 4, 7-17 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1, 3, 4, 7-17 and 35 are drawn to the determination of triglyceride level in lipoprotein by measuring the reaction of triglyceride-containing lipoprotein with a non-ionic surfactant that is synthesized from a block copolymer. However, the specification only discloses that this determination is suitable for low-density lipoproteins (LDL) triglyceride (page 3).

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. It is not realistic to expect that the "complete structure" could be described. In this case, the method of measuring triglyceride content can also determine other types of triglycerides. The claims encompass the technique in determining triglyceride level in high-density lipoproteins (HDL), intermediate density lipoproteins (IDL) and very low-density lipoproteins (VLDL). The specification discloses only the method of determining LDL triglyceride.

The limited disclosure in the specification is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of the genera recited in the claims at the time the application was filed. Applicants were not in possession of the methods of determining HDL, VLDL, or IDL concentrations in serum using the claimed methods since the specification is silent as to determining what polymers and method steps would yield the desired results. Moreover, the specification on page 3, as noted above, clearly indicates that this

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method is limited to LDL determination. Thus, it is concluded that the written description requirement is not satisfied for the claimed genera.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claim 1, at part (a) is unclear and indefinite it is recitation of "reaction" because it is uncertain as to the type of reaction being utilized, chemical or electrical.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shirakawa in view of Wieland et al, Pandya et al and Schmolka.

Shirakawa discloses a method of measuring a living body component by using cyclodextrin as an agent of soluble substance or as a stabilizing agent of an unstable substance and a nonionic surfactant such as polyoxyethylene (page 7 and 9) to coexist in the measuring process. Shirakawa teaches with a variety of surfactants with cyclodextrin derivatives (pages 8-9). Shirakawa has noted that the cyclodextrin and its derivatives are used with the surfactants to improve the solubility; as a result, the measuring of the living body component is accurate (pages 11-12). Shirakawa does not expressly disclose that the method of determining the living body component include the determination of triglyceride contained in lipoprotein. Shirakawa does not show the utilization of triblock copolymer of polyoxyethylene and polyoxypropylene with the molecular weight range from 1000 to 8000 as the nonionic surfactant. Nor does Shirakawa teach the addition of dextran sulphuric acids or its salts as an agent for the aggregation, presence of divalent metal ions, characterization of the enzymes with triosephosphate isomerase and glyceraldehydes 3-phosphate dehydrogenase.

Wieland et al disclose a method of determining triglycerides in protein fractions such as LDL, VLDL and HDL fractions. Wieland et al have shown that the composition used for the enzyme solution contains glycerokinase, glycerol-3-phosphated dehydrogenase, and triosephosphate isomerase (pages 9 and 13). Wieland et al further disclose that in the incubation period adenosine triphosphate (ADP) as phosphate group, nicotin adenine dinucleotide (NAD) as acceptor of reduction/oxidation, EDTA as calcium ion chelator, and $MgCl_2$ as magnesium salt are useful for achieving phosphorylation and as a color indicator (pages 9-10).

Pandya et al disclose that the tri-block copolymer polyoxyethylene (POE) as the end blocks and polyoxypropylene (POP) as the middle block is extensively used as a nonionic surface-active agents. Pandya et al have shown that the copolymer Pluronic 85 (P-85) with the molecular weight of 4500 in the solution was clear and fluid at higher temperature (page 187).

Schmolka discloses that when the percent of ethylene oxide increases or the molecular weight of the hydrophobe decreases then the solubility in water increases (page 111).

Schmolka further states that block polymer surfactants have many applications and one in particular is the separation of serum and poloxamer (page 115).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of increasing the solubility of an aqueous solution of a hydrophobic biological composition such as triglycerides as taught by Shirakawa by the method of Wieland et al. One would have been motivated to combine the tri-block copolymer of Pandya et al with Shirakawa to aid in solubilization of the triglycerides, since the tri-block is a nonionic surfactant as contemplated by Shirakawa. With regard to the claims limiting the tri-block copolymer to a specific molecular weight, it would have been obvious to modify the method of Shirakawa by the reason disclosed in the Schmolka reference to further increase the solubility of the composition in determining the triglycerides in lipoprotein. One would have been motivated to do so given that it would simplify the process of determining triglycerides in protein fraction with low cost (page 5 of Wieland reference). Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

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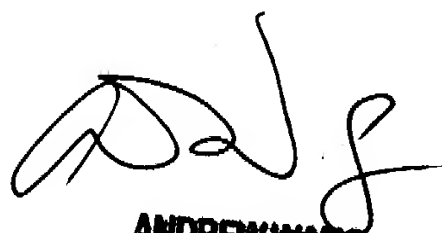
Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to June Hwu whose telephone number is (571) 272-0977. The Examiner can normally be reached Monday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JH


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